

ER/DL SPL Team Meeting

Minutes

April 14, 2010

Chair of today's meeting: Jessica Dunn Skorupski

Topics discussed

1. FDA Field Staff Inspection of Incoming API and Listing Concerns - Warren/Ava
 - a. Multiple sponsors have been contacted by DRLS asking the Sponsor to verify what company handles each "part" of the manufacturing process (note the ERDL data was submitted appropriately).
 - b. Does FDA really want API manufacturers to drug list separately? Port personnel are not accepting the final product Drug Listing.
 - i. Other companies have had the same issue with multiple Ports (ie., Miami, San Juan, Chicago, New York). Do they need further training?

Action: Group supports an organized effort to bring this issue to FDA. Warren to lead the drafting of a short statement of issue and examples for next meeting. Then he and Terry will forward statement to David Mazyck and Randy Levin.

2. Listing for import for packaging and subsequent export of bulk finished dosage form- Nadine
 - a. Import to Export situation - general consensus is this does not require a drug listing.
 - i. One company has always drug listed product that is exported. Others have not - Companies are handling this differently across the board.
 - ii. Jean -This group sent this question to DRLS and we are still waiting for final direction.

Action: Jean will re-send letter as follow up to David and copy Leyla.

3. Business Operations - Pat
 - a. Follow up with Leyla for definitions of business operations terms. Leyla responded in email – generally the intent of adding Packer and Labeler is related to our situation regarding 3rd parties brought in to just perform final packaging step. A Packer is any person who owns an independent establishment that performs packaging as a subcontractor. A Re-packer markets a finished product under it's own name and NDC numbers, they are not part of the manufacturing process

Action: Pat to post full response on wiki.

4. Where does the "revised date" on the bottom of the SPL come from?
 - a. Consensus is it the Effective time date entered by Sponsor.
5. What are people putting in as the Marketing Start date?
 - a. Some Sponsors use date of first SPL posting, which was advice from Lonnie. Some have gone back to files to find it. For new products it is easier to determine.

6. Some Sponsors have been requested, in FDA approval letters, to submit DL to OC within 14 days.
 - a. Consensus is regulations still allow Sponsors to use their discretion as to when is most appropriate time to drug list.
 - i. Reminder –Drug listing is required June and December.